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**Understanding whether BAME children have different symptoms when accessing
specialist CFS/ME services**

Statistical Analysis Plan

Version 1.0 (October 2020)

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Introduction

This document details the rules proposed and the presentation that will be followed, as closely as possible, when using data from the SMILE, MAGENTA and FITNET-NHS studies for this analysis.

The purpose of the plan is to:

1. Ensure that the analysis is appropriate for the aims of the study, reflects good statistical practice, and that interpretation of a priori and post hoc analyses respectively are appropriate
2. Explain in detail how the data will be handled and analysed to enable others to perform the actual analysis in the event of sickness or other absence

Additional exploratory or auxiliary analyses of data not specified in the protocol are permitted but fall outside the scope of this analysis plan (although such analyses would be expected to follow Good Statistical Practice).

The analysis strategy will be made available if required by journal editors or referees when the main papers are submitted for publication. Additional analyses suggested by reviewers or editors will, if considered appropriate, be performed in accordance with the Analysis Plan, but if reported the source of such a post hoc analysis will be declared.

Amendments to the statistical analysis plan will be described and justified in the final report of the study.

Study Design and Procedures

Background

To improve the access of specialist CFS/ME services for children from BAME backgrounds, we need to understand if their needs are different to non-BAME children so services can be adapted to suit their needs. We will look at the prevalence and describe the characteristics of BAME children attending specialist CFS/ME services.

Research Question

What are the clinical/demographic characteristics of BAME children compared to non-BAME children who access specialist paediatric CFS/ME specialist services?

Objective

To investigate and describe the baseline characteristics of children (those who identify as BAME and those who do not) with regards to demographic and clinical characteristics: co-morbidities, fatigue score, pain score

Study Design

This analysis will use routinely collected data from CFS/ME trials: The SMILE trial, MAGENTA and FITNET-NHS. Each data source includes demographic data, data on fatigue, disability, anxiety, depression and pain.

- SMILE: the SMILE trial has data on 100 children randomised to Specialist Medical Care or Specialist Medical Care plus the Lightning Process.^{1,2}
- MAGENTA has data on 220 children randomised to Graded Exercise Therapy or Activity Management³

- FITNET-NHS (PI Crawley) will have data on ~300 children randomised to online CBT or Activity Management.

Outcome Measures

- Baseline assessment form: symptoms, co-morbidities, time since onset, school attendance
- SF-36 physical function subscale⁴
- Chalder Fatigue Scale⁵
- Spence Children Anxiety Scale⁶
- Hospital Anxiety and Depression Scale⁷

Table 1: Measures to be analysed

Measure	SMILE	MAGENTA	FITNET-NHS
SF-36 Physical Function	X	X	X
Chalder Fatigue Score	X	X	X
Pain Visual Analogue Scale (VAS)	X	X	X
School Attendance	X	X	X
Hospital Anxiety / Depression Scale (HADS)	X	X	
Spence Children's Anxiety Scale	X	X	
Revised Children's Anxiety and Depression Scale			X

Analysis and Reporting

Data will be categorised based on ethnicity categories collected in the SMILE trial, MAGENTA and FITNET-NHS (Table 2).

Table 2: Ethnicity categories in the Datasets

SMILE	MAGENTA	FITNET-NHS
British	British	White
English	English	White/ Multiple ethnic groups (White and Black Caribbean/ White and Asian/ White and Black African/ Other Mixed)
Irish	Scottish	
Scottish	Welsh	
Welsh	Any other white background	Asian/ Asian British (Indian/ Pakistani/ Bangladeshi/ Chinese/ Other Asian)
Any other white background	White and black Caribbean	
White & black Caribbean	White and Asian	Black/ African/ Caribbean/ Black British
White & black African	Any other mixed background	Arab
White & Asian	Any other ethnic group	If any other ethnic group please specify (in box below)
Any other mixed background		
Indian		
Pakistani		
Any other Asian background		
Caribbean		

African		
Any other black background		
Chinese		

Two binary variables will be created from the ethnicity data captured in the trial data (Table 3):

- 1 = non BAME
- 2 = BAME

Table 3: Binary Coding of Ethnicity Data

SMILE	Binary Code	MAGENTA	Binary Code	FITNET-NHS	Binary Code
British	1	British	1	White	1
English	1	English	1	White/ Multiple ethnic groups	2
Irish	1	Scottish	1	(White and Black Caribbean/ White and Asian/ White and Black African/ Other Mixed)	
Scottish	1	Welsh	1		
Welsh	1	Any other white background	1		
Any other white background	1	White and black Caribbean	2	Asian/ Asian British (Indian/ Pakistani/ Bangladeshi/ Chinese/ Other Asian)	2
White & black Caribbean	2	White and Asian	2		
White & black African	2	Any other mixed background	2	Black/ African/ Caribbean/ Black British	2
White & Asian	2	Any other ethnic group	2		
Any other mixed background	2			Arab	2
Indian	2			If any other ethnic group please specify (in box below)	2
Pakistani	2				
Any other Asian background	2				
Caribbean	2				
African	2				
Any other black background	2				
Chinese	2				

Patient characteristics will then be described at first assessment at the clinic using the following categories:

- Age
- Gender
- Pain score
- Fatigue score
- School Attendance
- Co-morbid disorders (depression and anxiety, using Spence Children's Anxiety Scale, Hospital Anxiety and Depression Scale and Revised Children's Anxiety and Depression Scale)
- Severity of illness (SF-36 physical function subscale)

BAME children will be compared to non-BAME children to look for differences between the two samples in terms of the above characteristics (Table 4). Summary statistics of the baseline characteristics will be presented, in terms of means and standard deviations (if normally distributed) or median (IQR) if not.

Table 4: Reporting of the BAME and non-BAME patient characteristics

Category	Non-BAME (Code 1)	BAME (Code 2)
Age		
Gender		
Pain Score		
Fatigue Score		
School Attendance		
Comorbid Depression and Anxiety		
Severity of Illness		

References

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